

**COLD AND FLU NIGHTTIME SEVERE, 24-7 LIFE- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl tablet, film coated**

**Lil' Drug Store products, Inc.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Cold & Flu Nighttime Severe, 24/7 Life by 7-Eleven**

***Drug Facts***

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***Active Ingredients***

***Active Ingredients (in each caplet)***

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine HCl 5 mg

***Purpose***

***Purpose***

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

***Uses***

***Uses***

- temporarily relieves common cold and flu symptoms:
- minor aches and pains
- sinus congestion and pressure
- sore throat
- fever
- headache
- nasal congestion
- cough due to minor throat and bronchial irritation
- cough to help you sleep
- runny nose and sneezing
- reduces swelling of nasal passages
- promotes nasal and/or sinus drainage

- temporarily restores freer breathing through the nose

## **Warnings**

### **Warnings**

#### **Liver warning**

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

#### **Allergy alert**

**Allergy alert:** Acetaminophen may cause severe skin reactions.

Symptoms may include:

- blisters
- rash
- skin reddening

If a skin reaction occurs, stop use and seek medical help right away.

#### **Sore throat warning**

**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

#### **Do not use**

##### **Do not use**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients

#### **Ask a doctor before use**

##### **Ask a doctor before use if you have**

- liver disease
- diabetes
- thyroid disease
- heart disease
- glaucoma
- high blood pressure

- difficulty in urination due to enlargement of the prostate gland
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

### **Ask a doctor or pharmacist before use if**

### **Ask a doctor or pharmacist before use if you are**

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

### **When using this product**

### **When using this product**

- do not exceed recommended dosage
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic beverages
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

### **Stop use and ask a doctor**

### **Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

### **If pregnant or breast-feeding**

**If pregnant or breast-feeding**, ask a health professional before use.

### **Keep out of reach of children.**

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

### ***Directions***

### ***Directions***

- **do not take more than directed**
- do not take more than 8 caplets in 24 hours
- adults and children 12 years and over: take 2 caplets with water every 4 hours
- children under 12 years: ask a doctor

## ***Other information***

### ***Other information***

- **each caplet contains:** sodium 3 mg
- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

### ***Inactive ingredients***

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black iron oxide, corn starch, crospovidone, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

### ***Questions or comments?***

***Questions or comments? 1-877-507-6516***

## **Cold & Flu Nighttime Severe, 16ct, 24/7 Life - PDP/Package**

[24/7 Life logo]

### **Cold & Flu Nighttime Severe**

**Acetaminophen** / Pain Reliever/Fever Reducer  
Dextromethorphan HBr /Cough Suppressant  
Doxylamine Succinate / Antihistamine  
Phenylephrine HCl / Nasal Decongestant

**Relieves:** Headache, Fever, Sore Throat,  
Minor Aches & Pains, Nasal Congestion,  
Sinus Pressure, Sneezing, Runny Nose,  
Cough

compare to **Vicks**® **NyQuil**®  
**VapoCOOL**™ **SEVERE Cold &  
Flu + Congestion** active ingredients\*

**16**

CAPLETS

Actual Size [caplet image]



<p><b>Drug Facts (continued)</b></p> <ul style="list-style-type: none"> <li>temporarily restores freer breathing through the nose</li> </ul> <p><b>Warnings</b></p> <p><b>Liver warning:</b> This product contains acetaminophen. Severe liver damage may occur if you take</p> <ul style="list-style-type: none"> <li>more than 4,000 mg of acetaminophen in 24 hours</li> <li>with other drugs containing acetaminophen</li> <li>3 or more alcoholic drinks every day while using this product</li> </ul> <p><b>Allergy alert:</b> Acetaminophen may cause severe skin reactions. Symptoms may include: hives, rash, skin redness. If a skin reaction occurs, stop use and seek medical help right away.</p> <p><b>Sore throat warning:</b> If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.</li> <li>if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.</li> <li>if you have ever had an allergic reaction to this product or any of its ingredients</li> </ul> <p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>liver disease</li> <li>diabetes</li> <li>thyroid disease</li> <li>heart disease</li> <li>glaucoma</li> <li>high blood pressure</li> <li>difficulty in urination due to enlargement of the prostate gland</li> <li>a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema</li> </ul>	<p><b>Drug Facts (continued)</b></p> <ul style="list-style-type: none"> <li>cough that occurs with too much phlegm (mucus)</li> </ul> <p><b>Ask a doctor or pharmacist before use if you are</b></p> <ul style="list-style-type: none"> <li>taking sedatives or tranquilizers</li> <li>taking the blood thinning drug warfarin</li> </ul> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>do not exceed recommended dosage</li> <li>excitability may occur, especially in children</li> <li>marked drowsiness may occur</li> <li>avoid alcoholic beverages</li> <li>be careful when driving a motor vehicle or operating machinery</li> <li>alcohol, sedatives, and tranquilizers may increase drowsiness</li> </ul> <p><b>Step up and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>nevousness, dizziness, or sleeplessness occurs</li> <li>pain, nasal congestion, or cough gets worse or lasts more than 7 days</li> <li>fever gets worse or lasts more than 3 days</li> <li>redness or swelling is present</li> <li>new symptoms occur</li> <li>cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.</li> </ul> <p><b>If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.</b></p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>do not take more than directed</li> <li>do not take more than 5 caplets in 24 hours</li> <li>adults and children 12 years and over: take 2 caplets with water every 4 hours</li> <li>children under 12 years: ask a doctor</li> </ul>
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<p><b>Drug Facts</b></p> <p><b>Active ingredients (in each caplet)</b></p> <ul style="list-style-type: none"> <li>Acetaminophen 325 mg.....Pain reliever/fever reducer</li> <li>Dextromethorphan HBr 10 mg.....Cough suppressant</li> <li>Doxylamine succinate 6.25 mg.....Antihistamine</li> <li>Phenylephrine HCl 5 mg.....Nasal decongestant</li> </ul> <p><b>Purpose</b></p> <ul style="list-style-type: none"> <li>temporarily relieves common cold and flu symptoms:             <ul style="list-style-type: none"> <li>minor aches and pains</li> <li>sinus congestion and pressure</li> <li>sore throat</li> <li>fever</li> <li>headache</li> <li>nasal congestion</li> </ul> </li> <li>cough due to minor throat and bronchial irritation</li> <li>cough to help you sleep</li> <li>runny nose and sneezing</li> <li>reduces swelling of nasal passages</li> <li>promotes nasal and/or sinus drainage</li> </ul>	<p><b>Drug Facts (continued)</b></p> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>temporarily relieves common cold and flu symptoms:             <ul style="list-style-type: none"> <li>minor aches and pains</li> <li>sinus congestion and pressure</li> <li>sore throat</li> <li>fever</li> <li>headache</li> <li>nasal congestion</li> </ul> </li> <li>cough due to minor throat and bronchial irritation</li> <li>cough to help you sleep</li> <li>runny nose and sneezing</li> <li>reduces swelling of nasal passages</li> <li>promotes nasal and/or sinus drainage</li> </ul>
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<p><b>Drug Facts (continued)</b></p> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>each caplet contains: sodium 3 mg</li> <li>contains 16 caplets</li> <li>store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)</li> <li>see end flap for expiration date and lot number</li> </ul> <p><b>Inactive ingredients</b></p> <ul style="list-style-type: none"> <li>black iron oxide, corn starch,</li> </ul>	<p><b>Drug Facts (continued)</b></p> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>each caplet contains: sodium 3 mg</li> <li>contains 16 caplets</li> <li>store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)</li> <li>see end flap for expiration date and lot number</li> </ul> <p><b>Inactive ingredients</b></p> <ul style="list-style-type: none"> <li>black iron oxide, corn starch,</li> </ul>
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## COLD AND FLU NIGHTTIME SEVERE, 24-7 LIFE

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66715-6516
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>D&amp;C YELLOW NO. 10 ALUMINUM LAKE</b> (UNII: CQ3XH3DET6)	
<b>FD&amp;C BLUE NO. 1 ALUMINUM LAKE</b> (UNII: J9EA3S2JM)	
<b>STARCH, CORN</b> (UNII: O8232NY3S)	
<b>CROSPVIDONE, UNSPECIFIED</b> (UNII: 2S7830E561)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	

<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	

### Product Characteristics

<b>Color</b>	green	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	44;677
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66715-6516-8	2 in 1 CARTON	04/19/2022	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M012	04/19/2022	

**Labeler** - Lil' Drug Store products, Inc. (093103646)

Revised: 9/2023

Lil' Drug Store products, Inc.